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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,606	06/03/2005	Masato Yoshioka	4244-0106PUS1	3568

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EXAMINER	
FISHER, ABIGAIL L	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/537,606	YOSHIOKA ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks filed on July 31 200 is acknowledged. Claims 1-5 were amended. Claims 9-10 were added. Claims 1-10 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Rejections Necessitated by the Amendments filed July 31 2009

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 9 introduce new matter as the claim recite the limitation: "at least 0.1% by weight of one or more cosmetic formulation components". There is no support in the

specification for this limitation. The limitation of: "at least 0.1%" was not described in the specification as filed, and person skilled in the art would not recognize in the applicant's disclosure a description of the invention as presently claimed. While the specification does teach that the claimed cosmetic formulation components can be added and exemplify utilizing these cosmetic formulation components. The specification does not describe the instantly claimed range limitation. Applicants have indicated support is found at page 11, lines 9-12, page 11 lines 17-25 and examples 4-6 in Table 5 page 39 of the specification. While these claimed components are exemplified, none of them are exemplified in 0.1%. Therefore, the instant specification does not have support for the specific amount of 0.1%. Additionally, as claimed the amount of these cosmetic formulation components has no upper limit (as at least 0.1% means any amount of 0.1%). The instant specification does not have support for this type of upper limit. The examiner directs applications attention to MPEP 2163.05 III, which recites this specific type of amendment to range limitations. Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

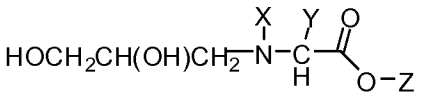
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Modified Rejection Based on amendments in the reply filed on July 31 2009

Claims 1-6 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Velisek et al. (J. Food. Science, 1991, cited in the Office action mailed on 4/2/09) in view of Carrell et al. (US Patent No. 5514808, cited in the Office action mailed on 9/22/08).

Applicant Claims

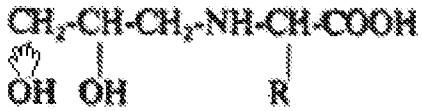
The instant application claims a composition comprising an amino acid N-glyceryl derivative that has the following formula (formula I):



where in X is a hydrogen; Y is a side chain of basic or neutral α-amino acids; and Z is a hydrogen, alkali metal, ammonium group, organic ammonium group or $CH_2CH(OH)CH_2OH$.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Velisek et al. is directed to 3-chloro-1,2-propanediol derived amino acids in protein hydrolytes. The main reaction product is identified by the following structure:



This compound was in a solution of pH 6, 8, 10, or 12. R corresponds to the side chain of amino acids which includes glycine, alanine, valine, leucine, isoleucine, phenylalanine, glutamate, aspartate, cysteine, methionine, lysine and proline (tables 2 and 3). Aqueous solutions contained 2.5 M of amino acids (page 140, model systems). These chemical hydroxylates are taught as being employed as seasonings for the improvement of flavor (page 139, first paragraph). Yields of the reaction for the formation of the glycerol derivative of glycine are shown in Table 1. Varying the pH of the reaction conditions as well as the reaction time directly effected the yield. At a pH of 6 and a reaction time of 1 day the yield was 10 mg/g where as a pH of 12 for 1 day gave a yield of 144 mg/g.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Velisek et al. do not teach that these compositions are capable of being utilized in cosmetics. However, this deficiency is cured by Carrell et al.

Carrell et al. is directed to hydroxyl ions as unique therapeutic agents. The compounds of the invention have the formula (column 4):

Compounds that are listed that particularly useful for the R^2 include H (which corresponds to glycine), CH_3 (alanine), $NH(CH_2)_3$ (ornithine), $H_2NCOCH_2CH_2$ (glutamine), as well as side chains corresponding to lysine, isoleucine, methionine, tryptophan, and valine (columns 8-9, lines 49-65 and 1-20). Y is taught as is a H or salt thereof such as lithium, potassium tetramethylammonium, etc. (column 5, lines 63-65).

It is taught that the compositions can be utilized to prove a dermal therapeutic effect (column 11, lines 58-67) and topical therapeutic effects (column 5, line 14). Formulations include ointments and creams (example 12). Exemplified amounts of the hydroxyl ion modulating compounds are from 1 to 15% of the total mixture (example 12). Other ingredients that may be added to the compositions as directed include, but are not limited to, dyes, pigments, perfumes, etc. up to a total of about 10% by weight. The compositions may contain constitutes normally present in preparations for application to human or animal tissue. These include emulsifiers, preservatives, etc. (column 10, lines 44-51).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143

Regarding the preambles of claims 1-6, the recitation of cosmetic, skin care cosmetic, and hair cosmetic have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable

weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Based on the teachings of Carrell et al. which teach that similar compounds can be utilized in cosmetics, there is a reasonable expectation that the solutions of Velisek are capable of being utilized in cosmetics. Therefore, it would have been obvious to one of ordinary skill in the art to utilize the compositions taught by Velisek in cosmetic formulations. Furthermore claim 1 recites the addition of a cosmetic formulation component. The compositions of Velisek et al. are aqueous solutions. Water would read on cosmetic formulation component.

Based on the structurally similarities of the compounds of Velisek and Carrell et al, i.e. both are directed to N-glycerol derivatives of amino acids and those of Carrell et al. possess two glycerol molecules attached while Velisek only possess one, one of ordinary skill in the art would have been motivated to utilize the compounds of Velisek in the same type of compositions as Carrell et al. One of ordinary skill in the art would have been motivated to add those ingredients taught by Carrell et a. which are customary to add in these types of compositions which include preservatives, perfumes and emulsifiers.

Regarding the claimed amount of the compounds of Formula I, table 1 shows a variety of different yields of the solutions of the N-glycerol. Lower yields shown

correspond to 10 mg/g or 1% where as upper limits correspond to 144 mg/g or 14%. Therefore, Velisek teach amounts that overlap those instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Velisek et al. in view of Carrell et al. and in further view of Berge (J. Pharmaceutical Sciences, 1977, cited in the Office action mailed on 4/2/09).

Applicant Claims

The instant application claims that groups Z is an organic ammonium groups of the formula NR_4^+, where R is selected from the group consisting of a hydrogen atoms, methyl, ethyl, hydroxymethyl, hydroxyethyl, 2-methyl1,3-propanediol-2yl and 2-methyl-1-propanolamine-2yl wherein at least one R groups is not a hydrogen atoms.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Velisek et al. are set forth above. Velisek et al. teach compositions comprising 3-chloro-1,2-propanediol derived amino acids. Carrell et al. teach compounds similar to that of Velisek et al. and their corresponding salts such as lithium, potassium and tetramethylammonium and that these compounds can be utilized in cosmetic type compositions.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Velisek et al. do not teach forming the corresponding ammonium salts of the 3-chloro-1,2-propanediol derived amino acids. However, this deficiency is cured by Berge et al.

Berge et al. is directed to pharmaceutical salts. It is taught that the chemical, biological, physical and economic characteristics of medicinal agents can be manipulated and often optimized by conversion to a salt form (page 1, first paragraph). Other reasons for choosing the salt form include stability, hygroscopicity and flowability of the resulting compound (page 1, second paragraph). Salts taught as suitable include aluminum, calcium, ethylenediamine, diethanolamine, etc. (Table 1).

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Velisek et al., Carrell et al. and Berge et al. and utilize ammonium salts such as diethanolamine salts of the 3-chloro-1,2-

propanediol derived amino acids. One of ordinary skill in the art would have been motivated to utilize the salt variety of these compounds in order to manipulate the chemical, biological, physical and economic characteristics of the agent as taught by Berge et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that (1) Velisek et al. disclose at page 142 that hydrolysates treated with 3-chloro-1,2-propanediol and heat can contain up to 10 mg/Kg of the amino acid derivatives and this equates to about 0.001% by weight. This limit fall out of the range instantly claimed. Applicants argue that (2) Carrell '808 is directed to N,N disubstituted compounds whereas those of formula I of the instant application is monosubstituted. Therefore, significant structural distinctions exist between the compounds of the formula of I and the compound disclosed by Carrell '808. Applicants argue that (3) the instant compounds can be employed in a cosmetic such as a cream in order to provide enhanced moisture absorption, moisturizing effects, gloss, moist feel, smoothness and compatibility. These effects may be obtained without requiring alkaline conditions. Applicants argue that (4) Carrell '808 cannot be combined with

Velisek et al. as Velisek et al. is directed foodstuffs whereas Carrell is directed to compositions used in wound treatments.

Applicants' arguments filed July 31 2009 have been fully considered but they are not persuasive.

Regarding applicants' first argument, in the section referred to by applicants (page 142) this is directed to analyzation of the components of soybean meal hydrolysates to prove the presence of the N-glycerol amino acids in the protein hydroslyates. Alternatively in Table 1 the reaction products and the corresponding yield of the N-glycerol glycine in solution were shown. As indicated above the amount range from 1% to 14%. These amounts overlap and therefore render obvious the claimed amounts.

Regarding applicants' second argument, the rejection does not cite the compounds of Carrell '808 as rendering the compounds of the instant invention obvious. Rather the rejection is based on the combination of Velisek et al. and Carrell '808. Velisek et a. teach compounds that are the same as instantly claimed. The difference between Velisek et al. and the instant claims is that the instant application claims the compounds in cosmetic compositions. The examiner maintains that this type of formulation would have been obvious based on the structural similarity between the Velisek et al. and Carrell' 808 compounds (i.e. mono vs. di substituted amino acids). In order to demonstrate patentability of the instant claims over that of Velisek et al., applicants must demonstrate that one of ordinary skill in the art would not expect the compounds of Velisek et al. to be utilized in the same manner as those of Carrell '808.

The examiner maintains one would have been motivated to utilize them in similar type of compositions (i.e. dermal wound compositions) based on their structural similarity. Sine Carrell '808 teaches that the compositions contain cosmetic formulation components such as emulsifiers, perfumes and preservatives. Therefore, these components would have been obvious to add to one of ordinary skill in the art based on the teachings of Carrell '808 and Velisek et al.

Regarding applicants third argument, it is noted that the features upon which applicant relies (i.e., effects with out having to add alkaline conditions) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding applicants' fourth argument, while Carrell '808 is not directed to food stuffs where as Velisek et al. is, due to the similar structural relationship between the claimed amounts (mono vs. di substituted amino acids) one of ordinary skill in the art would have been motivated to utilize the compounds of Velisek et al. in a similar type composition as to those compounds taught in Carrell '808. This provides the motivation to one of ordinary skill in the art to look to the teachings of Carrell '808 when looking for uses for the compounds of Velisek et al.

Once again the examiner would like to indicate to applicant that because of the similarity between the compounds of Velisek et al. and Carrell '808, one of ordinary skill in the art would have been motivated to utilize the compounds of Velisek et al. in those types of compositions taught by Carrell '808. Applicants must demonstrate (or

persuasively argue) why the compounds of Velisek et al. and Carrell '808 are not similar (either functionally, property wise, etc.).

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

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Primary Examiner, Art Unit 1616